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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,015	03/30/2000	Thomas R. Winston	15225-00041	7690

7590 08/13/2002

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EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/539,015

Applicant(s)

WINSTON ET AL.

Examiner

Shawna J. Shaw

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2002 and 30 May 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 5/2/02 have been fully considered but they are not persuasive.

Regarding applicant's argument that Tearney et al. and Swanson are directed toward imaging instead of guiding, the examiner contends that image data may be used for guiding and that the term "guiding" is broad in scope. Even more, the applicant admits in the specification that both blood flow information and *imaging* produced by the interferometric information are used to guide the guide wire (see page 8 lines 22-24). Thus, the examiner maintains that the interferometric guidewires of Tearney et al. or Swanson are capable of being "guided" within the structure/blood vessel with the acquired image data.

Applicant's amendments/arguments concerning a circuit configured to detect neovascular flow, an apparatus for detecting neovascular flow, and a method to detect neovascular flow - fail to distinguish how *neovascular* blood flow is detected differently from regular blood flow as taught by Tearney (col. 15 line 65 – col. 16 line 4). The examiner understands from the specification that the detection circuit measures the Doppler shift in frequency of light reflected from *tissue* (p. 3 lines 28-29), which Tearney does also (see col. 15 line 65 – col. 16 line 2). Thus, the applicant still has not structurally distinguished over the prior art by setting forth in the claims how

Art Unit: 3737

neovascular channels are detected differently from tissue containing blood vessels or how neovascular blood flow is detected differently from regular vascular flow.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., measurement of a velocity component in claim 14) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Tearney et al. and Peterson et al. are directed toward computerized interferometric analysis, and although Tearney et al. does not explicitly address a frequency to voltage converter, Tearney et al. does disclose a microprocessor for analyzing data (18). Peterson et al. teaches that the analyzer (590, col. 8 lines 59-63) comprises a frequency to voltage converter (col. 9 lines 18-20) and figure 9 shows an implementation of the analyzer coupled to an interferometer and bandpass filter (col. 7 line 64 – col. 8 line 17). It would have been obvious at the time the invention was made to a person of ordinary skill in

Art Unit: 3737

the art to use an analyzer configuration as taught by Peterson et al. comprising a frequency to voltage converter in the invention as taught by Tearney et al. to measure small velocity components (e.g., as small as red blood cells – col. 3 lines 53-54) and to discretize the obtained frequency data into meaningful values for analysis and/or comparison.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 17, it is unclear how the step of “utilizing linear changes in the signal path length so that the velocity path component is constant” is performed. In claim 17, “the signal path length,” “the velocity path component,” “the observed variance,” and “the sample component” lack antecedent basis. In claim 18, it is unclear whether “neovascular flow is determined” is a method step. In claim 18, “the interferometric system” lacks positive antecedent basis in that it has not been positively set forth in claim 14.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-4 and 7-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Tearney et al. of record.

Tearney et al. teach a method and apparatus for guiding a guide wire (34) through body tissue including an interferometric guidance system (4) and circuitry (18) for generating Doppler shift information (e.g., col. 15 line 65 - col. 16 line 8). Tearney et al. further teach an illumination source (2), first and second optical fibers (22, 32) wrapped around piezo electric transducers (90), a beam divider (6), a fixed reflector (12) and a detecting element (16). See also col. 5 lines 8-15 and col., 14 lines 22-29.

6. Claims 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanson et al. of record.

Art Unit: 3737

Swanson et al. teach a method for performing optical measurements including: performing a Doppler shift analysis (col. 9 lines 10-29, col. 12 lines 12-31 and claim 1) and utilizing either linear or sinusoidal changes in path length (col. 2 line 60 – col. 3 line 10 and col. 8 lines 37-64).

Claim Rejections - 35 USC § 103

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 5, 6, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tearney et al. in view of Peterson et al.

In regard to claims 5, 6, 12 and 13, Tearney et al. differ from the claimed invention in that a frequency to voltage converter is not explicitly addressed. Peterson et al. teach an apparatus for performing Doppler blood flow studies wherein processing

Art Unit: 3737

circuitry (590) includes a frequency to voltage converter (col. 9 lines 18-20). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use a frequency to voltage converter as taught by Peterson et al. in the invention as taught by Tearney et al. to facilitate computerized processing of frequency signals as is well known in the art. See also figure 9.

Drawings

10. The drawings are objected to because the boxes in the figures should be labeled. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nishizawa et al. (4,575,246) teaches that it is well known for interferometers to include frequency-to-voltage converters for generating voltages corresponding to the frequency of the signal to enable subsequent analysis and comparison by the digital components of the system (col. 2 line 66 – col. 3 line 5 and col. 4 line 64 – col. 5 line 18).

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3737

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

SJS

SJS
7/29/02


George Manuel